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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,339	08/28/2000	David A. Epstein	0942.4630001/RWE/BJD	8261

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EXAMINER
SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
1651	23

DATE MAILED: 02/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/650,339	Epstein et al.
Examiner	**Art Unit**
Sandra Saucier	1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 5, 2002*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-18, 20-37, and 44-61* is/are pending in the application.

4a) Of the above, claim(s) *5-7, 13, 28-30, 36, 48-53, and 56-59* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 8-12, 14-18, 20-27, 31-35, 37, 44-47, 54, 55, 60, and 61* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-18, 20-37, 44-61 are pending. Claims 1-4, 8-12, 14-18,20-27, 31-35, 37, 44-47, 54, 55, 60 and 61 are considered on the merits. Claims 5-7, 13, 28-30, 36, 48-53, 56-59 are withdrawn from consideration as being drawn to a non-elected invention. Claims 19, 38-43 have been canceled.

The elected species under examination is a hydroxypyridine derivative.

Claim Rejections - 35 USC § 112

NEW MATTER

Claims 1-4, 8-12, 14-18, 20-27, 31-35, 37 and 61 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In claims 1 and 24, the insertion of the limitation "with the proviso that said transition metal binding compound is not citrate", has no support in the as-filed specification. Claim 61 has a like intended recitation. The insertion of this limitation is a new concept because it does not have support in the narrative portion of the as-filed specification by way of generic disclosure, which would show possession of the concept of the exclusion of citrate with the inclusion of all other transition metal binding compounds. This is a matter of written description. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

Ex parte Grasselli *et al.* 231 USPQ 393 is considered by the examiner to be analogous to the present case because the common issue is whether **the composition** of the claims which is open to further inclusion of other elements or components not expressly excluded in the amendment is a new concept. In the instant case, as in *Ex parte* Grasselli, no support is found for this concept in the examples, originally filed claims or disclosure as-filed.

The instant examples do not support the exclusion of the complexing compound, citrate **and** the inclusion of all other complexing components. The originally filed claims are open to further substitution without limit (comprising). The generic disclosure of the instant specification under "Brief

Summary of Invention" also has open language (comprise) on page 7, line 19. Thus, the originally filed claims and disclosure support the inclusion of all transition metal binding compounds in the composition **including** citrate. Thus, applicants' specification demonstrates no intent to exclude citrate from the composition at the time of filing.

The exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.

While applicants may argue that none of the examples show the inclusion of citrate. However, the claims are not limited to the exemplified metal binding compounds in the exemplified compositions. The concept which has been introduced is the **exclusion** of a specific component (citrate) in the composition of the claims while the composition **remains open** to all further inclusions of transition metal binding components. This is the new concept. Please see *Ex parte* Grasselli *et al.* for further explanation.

Response to Arguments

Applicants argue that the exclusion of citrate as a metal binding compound was originally contemplated and offer as evidence, the absence of citrate as one of their preferred, specifically mentioned compounds in the description of the invention or as a specifically exemplified compound.

Applicants argue that *In re Johnson and Farnham* is pertinent case law. However, in this case, the excluded groups, E and E' are defined in the specification as part of the invention; thus, the excluded elements were fully contemplated at time of invention. In contrast, the instant applicants argue that their list of contemplated compounds does not include citrate, which is now inserted as a negative proviso in the claims. The conclusions rendered by the CCPA in *In re Johnson and Farnham* appears to support the examiner's conclusions concerning the new matter rejection at hand.

Applicants argue that *Ex parte Grasselli, et al.* was decided on a completely different set of facts as in the instant case. Applicants argue that In *Ex parte Grasselli*, it was found that the specification did not convey to persons of ordinary skill in the art that the inventor had possession of the claimed chemical process encompassed by the amended claims. In contrast, applicants

state that the instant specification describes several different compositions that comprise a transition metal binding compound that is not citrate.

However, the decision shows that while the Board found no basis for an enablement rejection of the claims, the Board found that the written description was not adequate to support the negative proviso although the examples do not contain what is excluded by the proviso. The instant argument that the excluded species, namely citrate, is not exemplified appears to be the argument that is strongly advanced by the applicants; however, such a fact pattern did not provide evidence for an adequate written description in *Ex parte Grasselli.*

In short, an inventor may carve out disclosed elements from his generic invention, that is he may claim less or fewer species, than what was **fully disclosed** as part of the invention, but he may not carve out elements which were not specifically disclosed as part of the original invention. The written description would not have conveyed to one having ordinary skill in the art that the applicant had possession of the concept now claimed, namely, the exclusion of citrate with the inclusion of all other metal binding compounds.

Claim Rejections - 35 USC § 112

Claims 14, 37, 44 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14, 37 recite "wherein said transition element complex is 2-hydroxypyridine-N-oxide.". This is indefinite because 2-hydroxypyridine-N-oxide is not a transition element complex. A complex requires both a chelator and a transition element.

Claim 44 is indefinite. It appears to have two closed groups, the components of which are somewhat repetitive. For example, the first grouping has transition element complexes as one choice, while the second grouping also has transition element complexes as one choice. The structure of the claim is unclear and the required components of the composition are thus, unclear. It appears that the composition AS CLAIMED may simply be a carrier and a transition element complex.

Claim 60 is indefinite because it is uncertain to what the Roman numerals refer in the independent claim.

Claim Rejections - 35 USC § 102

Claims 44-47, 54, 60, 61 remain/are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 5,328,913, Murad *et al.* [A].

The claims are directed to a kit which comprises a carrier and (either a medium OR a medium ingredient OR a transition element OR a transition element complex OR a cell) AND (either a transition metal binding compound OR a transition element complex).

Claim 60 is directed to a kit comprising a carrier, cell culture media (ingredients), transition element(s), transition element complex(es) and cell(s).

Murad *et al.* exemplifies the composition of 2-hydroxypyridine-N-oxide in DMEM with calf serum (Table I) and cells. DMEM is a standard cell culture media which contains at least one transition element such as Fe^{+3}, see Gibco Catalog [U]. Since 2-hydroxypyridine-N-oxide is a known chelator, see Sun *et al.* [V] or Kontoghiorghes [X], it is inherent in the nature of this molecule as with other molecules termed chelators, to complex or coordinate with transition metals and form an equilibrium between complex and free transition metals, when in solution with such metals. Thus, the composition of Murad *et al.* would inherently contain both free Fe^{+3} and the complex of 2-hydroxypyridine-N-oxide and Fe^{+3}. The citations [U], [V] and [AT3] merely show inherent ingredients and properties of elements found in the prior art citation of Murad *et al.*.

Applicants argue that Murad *et al.* does not disclose a kit. The claimed kit comprises a carrier and a medium which contains a transition metal ion and a complexing compound and a carrier. A carrier, that is a container, is inherent in the disclosure of a liquid composition. While applicant may point to the specification where "carrier" is defined, please note that the definition is open to other interpretations, "including", and limitations in the specification are not necessarily read into the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 44-47, 54, 60, 61 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Testa *et al.* [AT6].

Testa *et al.* disclose the composition of picolinic acid, a hydroxypyridine derivative, in RMPI with BSA and cells, see Material and Methods and Figure 1.

Applicants argue that Testa *et al.* does not disclose a kit. A carrier or a container is inherent in the disclosure of a liquid composition. Liquids always have carriers or containers whether explicitly disclosed or not.

Claims 1-4, 8, 11, 12, 15-18, 20-27, 31, 34, 35, 44-47, 54, 55, 61 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Waymouth [AR7].

The claims are directed to a serum free culture medium comprising a transition metal and a complexing compound and a kit which may comprise a carrier and a medium containing a transition metal and a complexing compound and a carrier.

Waymouth in Table 1 discloses a composition where a hydroxylpyridine derivative, pyridoxin, is a component of the medium. Compositions such as a medium always have carriers or containers and this is an inherent element in the composition disclosed.

Applicants argue that the examiner has not proven that pyridoxin is a chelator. However, applicants' claims may be interpreted to include pyridoxin in the recitation "a hydroxypyridine derivative". The examiner does not have to prove enablement of applicant's claims.

Claims 1-4, 8, 9, 11, 12, 15-18, 20-27, 31, 32, 34, 35, 44-47, 54, 60, 61 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Landschulz *et al.* [W].

Landschulz *et al.* disclose that ferric pyridoxal isonicotinoyl hydrazone can be substituted in serum free, chemically defined medium for transferrin. Table I shows MEM supplemented with ferric pyridoxal isonicotinoyl hydrazone at various concentration and mesenchymal cells.

All compositions disclosed in Landschulz et al. are in containers or carriers as containers for liquid compositions are inherent in the disclosure.

Claims free of the art

Claims 10, 14, 33 and 37 appear to be free of the art and will be allowed upon resolution of 112 issues.

Conclusion

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday, Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.

Sandra Saucier
Primary Examiner
Art Unit 1651
February 3, 2003